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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
HISSONG, BRUCE D

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,371	CEVC ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/29/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

1. The requirement for restriction, as detailed in the office actions mailed on 4/13/2005 and 1/10/2006, is hereby vacated in response the Applicants' arguments that the office action mailed on 4/13/2005 failed to demonstrate the lack of a special technical feature linking the claims of the instant invention.

2. In the amendments to the claims received on 10/17/2005, the Applicants cancelled claims 1-53 and added new claims 54-104. Accordingly, claims 54-104 are currently pending and are the subject of this office action.

Information Disclosure Statement

The information disclosure statement received on 10/29/2003 has been considered by the Examiner. Citations BR, CR, DR, ER, GR, and IR have not been considered because said citations are not in English.

Specification

The use of the trademarks Arlacel and Span (p. 27, last line), Transfersulin (p. 41, last paragraph), and Tween (throughout specification) has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

1. The Examiner suggests the syntax of claim 58 can be improved by amending the claim to read ".....further comprising a compound that is a cytokine or a compound that induces.....".

2. Claim 97 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim is drawn to a method of transnasally administering a pharmaceutical composition that is a vaccine, as set forth in claim 92, wherein at least one dose of the vaccine is administered. Because claim 92 is drawn to a method of administering a vaccine, and a vaccine must be administered at least once to stimulate an immune response in the recipient, the method of claim 92 would inherently involve at least one administration of the vaccine. Therefore claim 97, which also recites at least one administration of the vaccine, does not further limit the subject matter of claim 92.

Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of claims. Ex Parte Forman, (230 USPQ 546 (Bd. Pat. App. & Int. 1986); In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

1. Claims 54-104 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for administering a pharmaceutical composition to a patient in need, wherein said composition comprises an active ingredient that is a protein/peptide such as insulin, interferon (IFN)-γ, tetanus toxoid, GM-CSF, interleukin (IL)-4, IL-

12, cholera toxin, or heat labile toxin, does not reasonably provide enablement for a method of administering any other non-protein/peptide active ingredient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The breadth of the claims 54, 100, and 104 is excessive because the claims read on a method of transnasally administering a pharmaceutical composition comprised of any active ingredient. Thus, as currently written, the claims read on administration of an unreasonably large number of potential active ingredients by the claimed method of transnasal administration. The specification provides guidance and examples showing that the polypeptides insulin, IFN-γ, tetanus toxoid, GM-CSF, interleukin (IL)-4, IL-12, cholera toxin, and heat labile toxin can by transnasally administered by the claimed method, but do not provide guidance or examples for transnasally administering any other active ingredient. The specification recites numerous examples of active ingredients that theoretically can be administered by the method of the instant application, including polypeptides such as cytokines, bacterial and viral antigens, and various allergens, and also substances such as synthetic peptides and various drugs (p. 22-26). Although the teachings of the specification show that polypeptides can be transnasally administered by the claimed method and composition, the claims read on an active ingredient that can be non-protein in nature, such as nucleic acids, and small, non-peptide chemical molecules. Additionally, the claims are further drawn to active ingredients comprising pathogen-derived antigens or extracts, which could encompass protein antigens and extracts, but also extracts that are non-protein in nature, such as carbohydrates, lipids, and nucleic acids. There is no guidance or examples in the specification that show that any of these non-protein active ingredients, or any other non-protein active ingredient, can be efficiently transnasally administered by the claimed method, and if so, would have the desired or intended biological effect(s). A person of ordinary skill in the art would not be able to predict whether all possible active ingredients, including those of a non-protein nature, could be transnasally administered in a method that is commensurate in scope with the claims without further, undue experimentation.

2. Claims 54-104 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a penetrant comprising two substances, wherein the two substances are a surfactant that is Tween 80 or sodium cholate, and a lipid that is soybean phosphatidylcholine, does not reasonably provide enablement for a penetrate comprising any

other two substances. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The breadth of claims 54, 100, and 104 is excessive because the claims read on a pharmaceutical composition comprising a penetrant that is comprised of any two substances, provided that the substances differ in solubility, and/or form aggregates. As such, the claims read on an unreasonably large number of potential substances that can form the claimed penetrant of the pharmaceutical composition. The specification provides guidance and examples showing pharmaceutical compositions for transnasal administration, wherein said compositions comprise an active ingredient that is insulin, IFN-γ, tetanus toxoid, GM-CSF, IL-4, IL-12, cholera toxin, or heat labile toxin, and the two substances comprising the penetrant are the lipid phosphatidylcholine, and the surfactants Tween 80 or sodium cholate. Although the specification recites numerous lipids and surfactants that are presumably useful as components of the claimed penetrant of the pharmaceutical composition, there is no guidance or examples showing that these, or any other substances, can act as penetrants when combined together in a pharmaceutical composition for transnasal administration. Furthermore, a person of ordinary skill in the art would not be able to predict if any substances other than Tween 80 or sodium cholate, and phosphatidylcholine, could be used as a penetrant for transnasal administration of any active ingredient, and thus the skilled artisan would not know how to use any other substance, including any lipid and/or surfactant listed on p. 27 of the specification, without further, undue experimentation.

3. Claim 64 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of transnasally administering a composition comprising an active ingredient and a penetrant, wherein the penetrant is comprised of a more soluble substance that is an agent to be transported across a barrier, wherein the barrier nasal/mucosal membranes, does not reasonably provide enablement for an agent to be transported across any other barrier. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The breadth of the claim is excessive, because as written the claim reads on penetrant comprising a substance that can cross any type of barrier. The specification provides guidance

and examples of substances that can cross nasal/mucosal membranes, but does not disclose any penetrants that can cross any other type of barrier. Given the broadest possible interpretation, the recited barrier could be represented by latex gloves or a mechanical barrier. There is no guidance or examples in the specification that would teach one of ordinary skill in the art how to make and use a pharmaceutical composition comprising an active ingredient and a penetrant that is capable of crossing these types of barriers, or any other barrier other than nasal/mucosal membranes. Furthermore, one of ordinary skill in the art would not be able to predict which types of penetrants would allow materials to cross all types of biological, chemical, or mechanical barriers, and therefore would not be able to make and use the instant invention commensurate in scope with claim 64, without further, undue experimentation.

Claim Rejections - 35 USC § 112, first paragraph, written description

1. Claims 60 and is rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to derivatives or analogs of anti-cytokine antibodies. The claims do not require the derivatives or analogs of the anti-cytokine antibodies of the instant invention to have any biological activity other than possessing any-cytokine activity, nor any particular structure. Although the specification, on p. 32, teaches antibody fragments and such as single chain fragments, Fc-, Fab-, and $F(ab')_2$-fragments, the claim reads broadly on any antibody derivative or analog that possesses anti-cytokine activity. The specification does not teach or describe all possible derivatives or analogs of all possible anti-cytokine antibodies, and thus the claims are drawn to a genus of polypeptides that is defined only by having anti-cytokine activity.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a requirement that the derivatives or analogs have anti-cytokine activity. There is no identification of any particular portion of the anti-cytokine antibody that must be conserved in

order to maintain function. Accordingly, in the absence of sufficient distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

2. Claims 93 and 102 are rejected under 35 U.S.C. 112, first paragraph, containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to fragments or derivatives of a pathogen extract or compound, or an antigen "derived from" a pathogen. The claims do not require the fragments or derivatives of the instant invention to have any biological activity, nor any particular structure. Thus, the claims are drawn to a genus of compounds that has not been adequately described in the specification.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claims is a requirement that the fragments or derivatives are fragments or derivatives of any pathogen extract or compound, or are an antigen derived from a pathogen. There is no identification of any particular portion of any derivative of a pathogen-derived antigen, or any pathogen extract or compound that must be conserved in order to maintain function. Accordingly, in the absence of sufficient distinguishing characteristics, the specification does not provide adequate written description of the claimed genus.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 54-104 are indefinite because the elements recited in claims 54, 100, and 104 do not constitute proper Markush groups. The claims are indefinite in the alternative use of

"and/or" because it is not clear what controls which of these limitations. See MPEP § 2173.05(h).

2. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites a pharmaceutical composition for transnasal administration comprising at least two substances, wherein the at least two substances are "two forms" of a substance. The specification, on p. 14, defines "two forms of a substance" as two ionization states or salt forms of the same substance, two different complexes of such substance, **etc**" (emphasis added). Because the definition provided by the specification is open-ended in regards to "etc", it is not clear what else could be constitute "two forms of a substance", and thus the metes and bounds of the claim are not defined.

3. Claim 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite because it is not clear how an anti-cytokine *activity* can be associated with the penetrant. Thus, it is not clear if the activity is physically associated with the penetrant, or the penetrant itself possesses anti-cytokine activity, or the cytokine or compound that possesses anti-cytokine activity is associated with the penetrant, or something else.

4. Claim 64 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites an agent to be transported across a "barrier", and also recites an agent forming "common large structures." The metes and bounds of the phrase "common large structures" are not defined by the claim, and therefore the intended meaning of the phrase is not clear, thus rendering the claim indefinite. Similarly, the metes and bounds of the recited "barriers" are not defined by the claim. In the instant case, a "barrier" could encompass the barrier formed by the nasal membranes, or a mechanical barrier consisting of non-biological material (e.g. latex rubber or a similar material).

5. Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. The claim recites the phrase "surfactant-like molecule". The intended meaning of the term "surfactant-like" is not clear. Therefore, the metes and bounds of the phrase are not defined by the claim.

6. Claim 81 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the phrase "practically sufficient penetrant stability". Although the specification, on p. 29, states that this term means that the penetrant stability meets the reasonable product quality criteria, this definition is insufficient to define the metes and bounds of the term because neither the specification or claims define or limit the criteria for "reasonable product quality".

7. Claims 83-86 recite the limitation "the relative drug or agent". There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 104 is rejected under 35 U.S.C. 102(b) as being anticipated by Cevc *et al* (Biochem Biophys Acta, Jan 19, 1998, Vol 1368(2), p. 201-215 – cited in the information disclosure statement received on 10/29/2003). The claim is drawn to a pharmaceutical composition for transnasal administration comprising an active ingredient and a carrier comprising a penetrant, wherein the penetrant comprises a minute fluid droplet surround by a coating of at least two substances.

Cevc *et al* disclose a pharmaceutical preparation for delivering insulin across the skin barrier. The composition taught by Cevc *et al* comprises insulin as an active ingredient, and is further comprised of soybean phosphatidylcholine and sodium cholate (see p. 203, section 2.5). Thus, the composition taught by Cevc *et al* meets the limitations in the claim that the composition comprise an active ingredient and two additional substances. Cevc *et al* does not

specifically teach that the phosphatidylcholine and sodium cholate components differ by a factor of 10 in solubility in a liquid medium, forms homoaggregates of one substance or heteroaggregates with at least two substances, or the more soluble substance (i.e. the surfactant – sodium cholate) solublizes the droplet, and the content of the more soluble substance is up to 99 mol-% of the concentration required to solublize the droplet or corresponds to up to 99 mol-% of the saturating concentration in an unsolubilized dropet, or finally, that the elastic deformation energy of the droplet surrounded by the coating is at least five times lower than the deformation energy of red blood cells or of a phospholipids bilayer having fluid aliphatic chains. However, it is noted that the specification of the instant invention contains examples of compositions comprising insulin as the active ingredient, and a penetrant comprised of soybean phosphatidylcholine and sodium cholate. Therefore, without evidence to the contrary, the composition taught by Cevc *et al* would be expected to inherently possess these characteristics, and thus meet these limitations of the claim. Furthermore, because the Office does not have the facilities for testing the characteristics of the composition taught by Cevc *et al*, the burden is on the applicant to show a novel and unobvious difference between the claimed pharmaceutical composition for transnasal administration, and that of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Finally, although the pharmaceutical composition taught by Cevc *et al* is not specifically disclosed as a composition for transnasal administration, it is noted that it is virtually identical to the compositions described in the examples of the instant specification, and without evidence to the contrary, would inherently be a composition for transnasal administration of insulin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 54-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cevc *et al,* in view of Drejer *et al* (*Diabetic Med*, 1992, Vol. 9, p. 335-340 – cited in the information

disclosure statement received on 10/29/2003), and further in view of Hussain *et al* (US 4,383,993). The claims of the instant invention are drawn to a method of administering a pharmaceutical composition to a patient in need thereof, with said method comprising transnasally administering a pharmaceutical composition comprising an active ingredient and a carrier comprising a penetrant, with said penetrant comprised of at least two substances. The teachings of Cevc *et al* as they relate to a pharmaceutical composition are described in the 35 U.S.C. 102 rejection above. Cevc *et al* is silent regarding a method of transnasally administering a pharmaceutical composition.

Drejer *et al* teaches methods of intranasal administration of a composition comprising insulin as the active ingredient, and further comprising phosphatidylcholine in a sodium phosphate buffer (see abstract and p. 335-336 – "Subjects and Methods"). Drejer *et al* discloses that nasal administration of the composition comprising insulin and phosphatidylcholine was effective in delivering insulin to the patients and resulted in a faster time-course of absorption compared to subcutaneous injection (see abstract and p. 337-339). Drejer *et al* does not teach the use of a surfactant in the composition for intranasal administration. However, Hussain *et al* does teach the use of a surfactant in a composition for nasal administration. Hussain *et al* teaches compositions comprised of progesterone or 17-β-estradiol, and further comprised of the surfactant Tween-80 and isotonic saline (see Examples 1-6), and also teaches a method of intranasally administering a composition comprised of progesterone and Tween-80 (column 3, lines 33-63). Hussain *et al* also teaches that the method of nasal administration resulted in a greater bioavailability of the progresterone compared to oral or intravenous administration, and that progesterone administered nasally was absorbed very rapidly (column 3, line 64 – column 4, line 31).

A person of ordinary skill in the art, at the time the instant invention was conceived, would have been motivated to combine the teaching of Cevc *et al* with those of Drejer *et al* and Hussain *et al* to practice a method of transnasally administering a pharmaceutical composition comprised of an active ingredient and further comprising a penetrant of at least two substances. The motivation to do so comes from Drejer *et al*, which teaches that nasal administration of an active ingredient, insulin, is effective when the insulin is combined in a composition with the lipid phosphatidylcholine in a sodium phosphate buffer, and Hussain *et al*, which teaches that nasal administration of progesterone is effective when combined with the surfactant Tween-80 in isotonic saline. Thus, the combined teachings of Drejer *et al* and Hussain *et al* teach that

phosphatidylcholine and Tween-80 are essential components for compositions for nasal administration of bioactive polypeptides. Because both phosphatidylcholine and Tween-80 have individually been shown to be effective, one of ordinary skill in the art would be motivated to combine the reagents in a single composition for nasal administration, and therefore would be motivated to use the composition taught by Cevc *et al* for transnasal administration. Although Cevc et al does not specifically teach transnasal administration, the skilled artisan would know, based on the teachings of Drejer et al and Hussain et al, that the composition taught by Cevc et al would be effective as a composition for transnasal administration, and would have the motivation to use it in such a way. Furthermore, although Cevc *et al*, Drejer *et al*, and Hussan *et al* does not specifically teach compositions with a specific penetrant diameter, concentration, or pH, specific active ingredient concentration, or specific electrolyte concentration of any supporting medium, one of ordinary skill in the art would have the motivation and the technical ability to optimize these conditions in order to create a composition that is effective in delivering bioactive agents by transnasal administration. Additionally, a skilled artisan would also be able to optimize the dosage of the composition administered to individual patients, and would also be motivated to administer the composition using a metered delivery device, which are well-known in the art.

In summary, by following the teachings of Cevc *et al*, Drejer *et al*, and Hussain *et al*, the skilled artisan would have both the motivation, and a reasonable expectation of success, in practicing a method of transnasally administering a pharmaceutical composition comprising an active ingredient such as insulin, and further comprising a penetrant comprised of phosphatidylcholine and Tween-80, wherein said method and pharmaceutical composition are commensurate in scope with the claims of the instant invention.

Conclusion

No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be

reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH
Art Unit 1646

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PRIMARY EXAMINER